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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,793	10/01/2001	Benedito Da Silva	TIN-0017	5160

23413 7590 07/03/2003

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EXAMINER

COOK, REBECCA

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 07/03/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Applicati n N .

09/868,793

Examin r

Rebecca Cook

Applicant(s)

DA SILVA, BENEDITO

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 13/3/03.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 11,12,17,20-22,24 and 27-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11,12,17,20-22,24 and 27-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10, 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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The amendment filed on March 3, 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the amount "104.0 ml" on line 12 in the replacement to the second full paragraph on page 2 of the Substitute Specification. This is a new matter rejection.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claims 28-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. No support is seen in the original specification for the recitation "upper respiratory infection."

Claims 12, 17, 20-22, 24, 27-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The intent of the recitation "balanced mixtures" in claims 12 and 28 is not understood and the specification does not define it. Furthermore, the term "mixtures" makes it appear that more than one mixture is required. Amending it to recite "a mixture" will overcome this rejection.

In claim 24 the Markush recitation "or a fine powder" is incorrect. Amending it to recite "and a fine powder" will overcome this rejection.

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In claims 29 and 32 the intent of recitation "wherein the upper respiratory infection results in sinusitis or rhinitis" is not clear. Is the intent to recite "wherein the upper respiratory infection is sinusitis or rhinitis?"

The recitation "nasal releaser" in claim 17 appears to be colloquial. Replacing it with the recitation "used to exfoliate the mucosa of the nasal passages" would make the claims more clear. This is supported in the original specification on page 2.

In view of the amendments to the claims and specification the earlier objections and rejections under 35 USC 112, paragraphs one and two are overcome.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-12, 17, 20-22, 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE 27 21 014 (Reith) for the reasons given in Paper No. 8.

Applicant's argument that Reith does not teach a method for treating sinusitis and rhinitis is not persuasive. Sinusitis and rhinitis are common airway manifestations of allergies and viral infections. Furthermore, applicant has not argued that once a method of using a compound is known it would be obvious to one of ordinary skill in the art to determine the optimum amount of the active agent and the vehicle system.

Claims 27-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE 27 21 014 (Reith). Reith (abstract, lines 1-7) discloses that alpha-hydroxy propionic acid can be used to treat allergies and viral diseases. The instant claims differ over the

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reference in reciting and upper respiratory infection, amounts of the active ingredient and specific vehicles. However, an upper respiratory infection is a common manifestation of a viral infection. Additionally, in the absence of a showing of unexpected results, once a method of using a compound is known it would be obvious to one of ordinary skill in the art to determine the optimum amount of the active agent and the vehicle system.

In the IDS submitted on March 6, 2003 the Myrivik reference was not considered because it is an improper citation: the title and date of publication were not provided.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (703) 308-4724. The examiner can normally be reached on Monday through Thursday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

  
REBECCA COOK  
PRIMARY EXAMINER  
GROUP 1200/614

July 2, 2003